Testimony on S.B. 308 / H.B. 291

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Thank you for the opportunity to testify on S.B. 308 / H.B. 291, legislation to permit the use of marijuana for medical purposes in Maryland. I am joined by Wendy Kronmiller, Chief of Staff and Assistant Secretary for Regulatory Affairs, and Frances Phillips, Deputy Secretary for Public Health.

In this testimony, I will provide some background on the scientific evidence on the use of marijuana for medical purposes.

I will also discuss several challenges of implementing S.B. 308 / H.B. 291. Because of these issues, the Department opposes this legislation as drafted.

The Department is willing to participate in a study this year to identify a more feasible option for the use of marijuana for medical purposes in Maryland.

Background: The Use of Marijuana for Medical Purposes

It is well known that marijuana contains pharmacologically active compounds, called cannabinoids, that have therapeutic value. These include tetrahydracannabinol, known as THC, and cannabidiol.

Some of these compounds have been isolated, studied, and approved by the U.S. Food and Drug Administration for specific indications. For example, Marinol (dronabinol) and Cesamet (nabilone) are indicated for treatment of severe nausea and vomiting patients receiving cancer chemotherapy. Marinol is also indicated for loss of appetite and weight loss in AIDS. An oral spray called Sativex (nabiximol) is now being studied in clinical trials.

The use of the marijuana plant itself for medical purposes is controversial. This is not just because marijuana is a controlled substance. It is also because marijuana, unlike approved pharmaceuticals, has not been characterized, studied, and determined by the U.S. Food and Drug Administration to be safe and effective.[1]

[1]When FDA considers a pharmaceutical for approval, the agency's scientists review the raw data from clinical studies, inspect the study reports and study sites, and often present data to advisory committees with

Many patients with severe and chronic illness have reported that marijuana helps their symptoms, and in some cases, that only marijuana helps their symptoms. Other patients have suffered adverse reactions, including memory problems, severe anxiety, panic attacks, psychosis, and other medical complications. Some scientific studies have reported effectiveness for specific conditions, others have failed to find effectiveness or found harm.

Considering the existing body of evidence, scientists and medical organizations have taken one of three differing approaches.

The first approach is a **green light** to multiple medical uses of marijuana. Scientists who support this approach have concluded that marijuana is effective for a wide range of disorders, the benefits outweigh the risks, and that marijuana should be broadly available as a medical treatment now. As one doctor is widely reported to have stated, "Cannibis will one day be seen as a wonder drug, as was penicillin in the 1940s. Like penicillin, herbal marijuana is remarkably nontoxic, has a wide range of therapeutic applications, and would be quite inexpensive if it were legal."

A second, contrasting approach is a **red light** until better data become available. Several leading medical organizations in the United States have supported additional research and independent regulatory review, but they have <u>not</u> supported state efforts to legalize marijuana for medical use. For example:

- In 2009, the Council on Science and Public Health of the American Medical Association stated that therapies should pass a rigorous, evidence-based review by an independent regulatory agency and opposed "drug approval…by ballot initiative or state legislative action."[2] The AMA has <u>not</u> taken a position in favor of state efforts to legalize marijuana for medical uses.

- In 2010, the American Society for Addiction Medicine stated that marijuana "should be subject to the same standards that are applicable to other prescription medications and medical devices and that these products should not be distributed or otherwise provided to patients unless and until such products or devices have received marketing approval from the Food and Drug Administration."[3]

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independent experts. The use of marijuana for medical purposes has not passed such a review in the United States.

[2]The Council on Science and Public Health "supports the concept of drug approval by scientific and regulatory review to establish safety and efficacy, combined with appropriate standards for identity, strength, quality, purity, packaging, and labeling, *rather than by ballot initiative or state legislative action*." [emphasis added]. See Council on Science and Public Health, American Medical Association. *Use of Cannibus for Medicinal Purposes.* CSAPH 3-1-09.

[3] American Society of Addiction Medicine. *Public Policy Statement on Medical Marijuana*. April 2010.

The third approach is a **yellow light.** This intermediate approach sees the evidence for specific uses of marijuana as promising but not definitive and supports the limited use of marijuana for medical purposes as part of a monitored research program.

In 1999, a committee of the Institute of Medicine of the National Academy of Sciences issued a comprehensive study called "Marijuana and Medicine: Assessing the Science Base."[4] This study determined that "scientific data indicate the potential therapeutic value of cannabinoid drugs … for pain relief, control of nausea and vomiting and appetite stimulation." However, the study also found that "smoked marijuana … is a crude THC delivery system that also delivers harmful substances."

The Institute of Medicine committee found that along with potential benefits of marijuana, there are potential risks to patients, including immediate psychological adverse effects and chronic health effects, such as cancer, lung damage and poor pregnancy outcomes.

Balancing the potential benefits with the potential risks, the Institute of Medicine committee supported the availability of marijuana for medical purposes through research programs with specific controls, including:

1. Treatment of less than six months duration;
2. Failure of all approved medications to provide relief has been documented;
3. The symptoms can be reasonably expected to be relieved by rapid-onset cannabinoid drugs;
4. Such treatment is administered under medical supervision in a manner that allows for assessment of treatment effectiveness; and
5. Involves an oversight strategy comparable to an institutional review board process that could provide guidance within 24 hours of a submission by a physician to provide marijuana to a patient for a specified use.

For such studies, the Institute of Medicine committee recommended that patients receiving marijuana to smoke be "fully informed of their status as experimental subjects using a harmful drug delivery system." The Committee ultimately supported the development of more purified and safe delivery mechanisms for cannabinoids.

Several other medical organizations have generally supported this "yellow light" approach at this time. For example, in 2008, the American College of Physicians issued a statement entitled "Supporting Research into the Therapeutic Role of Marijuana." The College endorsed the Institute of Medicine's recommendations for clinical studies.[5]

Analysis of S.B. 308

[4] Institute of Medicine. *Marijuana and Medicine: Assessing the Science Base*. 1999.

[5] American College of Physicians. *Supporting Research into the Therapeutic Role of Marijuana*. 2008.

This legislation would legalize marijuana for medical use in Maryland. The Department appreciates the detail of the bill and recognizes that its goal is to permit patients access to marijuana for medical purposes while minimizing the potential for diversion to illegal markets.

The legislation establishes an extensive regulatory structure for marijuana for medical purposes in Maryland. Among other tasks, the legislation requires the Department of Health and Mental Hygiene to establish security and safety standards for growers and transportation; establish standards for consistency, adulteration, and contamination of the marijuana plant; oversee a laboratory testing program; conduct a study to estimate demand for marijuana for medical purposes; establish and enforce regulations on criminal history checks and periodic drug testing; adopt and enforce standards for marijuana cultivation; conduct an RFP to select growers; select locations for growing; establish an IT system to track the amount of marijuana dispensed and to whom; license dispensaries; review applications for eligibility by patients and caregivers; issue identification cards to patients and caregivers; verify the information in applications for patients and dispensaries; monitor appropriate clinical care by physicians; and oversee the pricing of marijuana.

Resources. The Department estimates that these tasks will require a separate office or administration to administer. The number of patients and dispensaries that will participate in Maryland is unknown, and studies will have to be conducted before reliable estimates can be developed. In states less populous than ours, more than 1,000 dispensaries distribute marijuana and more than 100,000 patients are eligible to receive it. Oversight of such a large system would require a significant investment in infrastructure.

In addition, some of the tasks assigned to the Department, such as establishing standards for consistency, adulteration, and contamination, appear to break new ground scientifically. As a result, regulations in this area will require new expertise and time to develop.

Our initial review of the resource needs for our Department to handle these responsibilities in the legislation as written found that the cost would easily reach at least several million dollars, with revenues delayed and of uncertain quantity.

Timing. Because the scientific standards would have to be in place before the RFP for growing could be drafted, and because the RFP process would have to be complete before the growing could begin, the Department estimates that it would be at least several years before marijuana for medical purposes would be available in Maryland.

Effectiveness. The Department appreciates that this legislation has been drafted to provide patients access to marijuana for medical purposes free of criminal sanction while minimizing concerns about diversion to illegal markets. As it stands, marijuana is the most common drug reported by individuals age 20 and under admitted to treatment programs in our state, with more than 6000 admissions each year (and rising over the last three years).

Nonetheless, despite the regulatory structure established by the legislation, the Department has concerns that the bill may not achieve its intended goals.

From the perspective of patients interested in trying marijuana for medical purposes without criminal sanction, the legislation provides for serious penalties for failure to comply with the various rules and procedures. For example, it states that any person who makes a "material misstatement" in an application is guilty of a misdemeanor and on conviction "is subject to imprisonment not exceeding 1 year or a fine not exceeding $1,000 or both." Enforcement of this legislation may wind up leading to more court cases and more severe penalties against patients than exist today, not fewer.

From the perspective of diversion, the law as drafted does not provide for meaningful limits on (1) which doctors can recommend marijuana for medical uses; (2) the conditions for which marijuana can be recommended; (3) the number of dispensaries; (4) the duration of treatment; or (5) the quantity of marijuana to be provided. Nor does the legislation include any of the five recommendations of the Institute of Medicine under the "yellow light" approach.

Unintended consequences. The Department also notes that there is a prohibition on any entity that distributes marijuana hiring anyone with a criminal conviction for drug possession. Depending on who chooses to apply for a license to dispense, this provision could lead to individuals in recovery being dismissed from current employment.

Next Steps

The Department is willing to participate in a study this year to identify a more feasible option for the use of marijuana for medical purposes in Maryland. Specifically, the Department is open to working with the legislation's sponsors, interested parties, the medical community, and law enforcement to determine whether there is "yellow light" model for Maryland that balances the potential benefits of marijuana for medical purposes with the potential risks and which provides for a more feasible oversight function for the Department.

Thank you for the opportunity to testify, and we look forward to your questions.